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**APPLICATION NUMBER: 60/554,018**

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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET


This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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INVENTOR(S)					
Given Name (first and middle [if any])		Family Name or Surname		Residence (City and either State or Foreign Country)	
Landon		Miller		Tuscaloosa, Alabama	
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max)					
SYSTEM AND METHOD FOR NEUROLOGICAL INJURY DETECTION, CLASSIFICATION AND SUBSEQUENT INJURY AMELIORATION					
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<input checked="" type="checkbox"/> Customer Number		25006		 Place Customer Number Bar Code Label here PATENT TRADEMARK OFFICE	
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification	Number of Pages	5	<input type="checkbox"/> CD(s), Number		
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	1	<input checked="" type="checkbox"/> Other (specify)	CLAIMS - 3 pgs. ABSTRACT - 1 pg.	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input checked="" type="checkbox"/>	Applicant claims small entity status. See 37 CFR 1.27.			FILING FEE AMOUNT (\$)	
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
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Respectfully submitted,

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Date 3/17/04  
REGISTRATION NO. 39,204  
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Docket Number: NRI-10618/22

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## SYSTEM AND METHOD FOR NEUROLOGICAL INJURY DETECTION, CLASSIFICATION AND SUBSEQUENT INJURY AMELIORATION

### TECHNICAL FIELD

The present invention generally relates to the immediate treatment of neurological injuries. More specifically, the present invention relates to a system and method for actively and passively detecting and analyzing neurological damage in an injured person using electrical and chemical analyses supported by a computer system and database, selecting an appropriate neurologically protective pharmaceutical for that injury type and circumstances based on the result of said analyses, and then delivering this pharmaceutical via direct injection, intravenous delivery, or other means into the person using components of the kit of which all the elements of the invention are a part.

### BACKGROUND OF THE INVENTION

In the United States, there are approximately 500,000 new cases of Traumatic Brain Injury (TBI) admitted to hospitals in the United States each year, and the incidence requiring hospitalization is estimated to be approximately 200 to 225 per 100,000 population. Currently, it is estimated that brain injuries account for 12% of all hospital admissions in the United States. Spinal Cord Injuries (SCI) account for another 10,000 cases per year.

Transportation-related injuries of all types are responsible for approximately 50% of TBI within the United States. The costs of severe TBI to the individual, family, and society are extremely high. Extrapolation of the data from studies results in an estimated 26,000 trauma deaths per year, with another 20,000 to 45,000 patients suffering significant physical or

neurobehavioral sequelae resulting in functional loss, and the direct costs are over \$25 billion annually. The average direct hospital charges were estimated to be \$117,000 per admission in 1993 within the Traumatic Brain Injury Model Systems. One can easily determine that TBI is an extraordinary medical care problem within the United States that is closely comparable in morbidity, mortality, and economic loss to human immunodeficiency virus infection; yet it is a very understudied mechanism of morbidity and mortality in the United States as well as worldwide, at autopsy.

Currently, there exists no system, process or method for treating such injuries at the scene of such incidents except for rudimentary techniques such as immobilization and physical stabilization. While helpful, research has shown that cell death in the brain and spinal cord starts almost immediately. It is estimated that 40% of all damage is done in the first 10 minutes after injury and most initial damage is done in four hours. Yet there is no present system or method for at least ameliorating such damage inside the treatment time window.

Accordingly, it would be advantageous and desirable to have a system and method of detecting and analyzing neurological injuries and providing immediate, ameliorating treatment while overcoming the drawbacks and disadvantages of any somewhat related prior art.

## SUMMARY OF THE INVENTION

According to the present invention, there is disclosed a system and method for actively and passively detecting and analyzing neurological damage in an injured person using electrical and chemical analyses supported by a computer system and database, selecting an appropriate neurologically protective pharmaceutical for that injury type and circumstances based on the

result of said analyses, and then delivering this pharmaceutical via direct injection, intravenous delivery, or other means into the person using components of the kit of which all the elements of the invention are a part.

#### DETAILED DESCRIPTION OF THE INVENTION

5           The present invention provides a system and method for detecting, analyzing and then ameliorating further injury to a person's neurological system once that person has suffered such an initial injury. The system provides detection and analysis support to classify such injury, and the method of the present invention includes selecting the correct neuroprotective pharmaceutical from a preexisting kit of such pharmaceuticals, and then delivering via a variety of means that  
10           pharmaceutical into the injured person.

          The terms "person" and "subject" mean all animals including humans. Examples of patients or subjects include humans, cows, dogs, cats, goats, sheep, and pigs.

          Those skilled in the art are easily able to identify patients or subjects who have sustained neurological injuries including, but not limited to, conditions such as unconsciousness or  
15           inability to move.

          The system and method of the present invention includes attaching emitters to pre-designated areas of the body, for example, but not limited to, an area of the ear which has a nerve which is bundled to the nerves running to muscle groups in the back of the calf, attaching sets of detectors to other areas of the body, for example, but not limited to, a muscle group in the back  
20           of the calf, and then emitting small amounts of electrical current into the emitter and determining if there is a complete circuit in the body; i.e., determining if there is such nerve damage that the

signal cannot be detected as a result of the possible injury, as well as analyzing such signals against a database of such signals for the muscle group to determine the percentage of such signal strength compared to the norms of the database, while also sampling blood and other tissues to detect the presence of certain chemical and biological substances which indicate the presence of different types of neurological injuries, and finally, using the results of the detection and analysis, providing guidance to the analyzing person in the field about which particular pharmaceutical should be selected, from a variety of prepackaged neuroprotective pharmaceuticals, and suggesting which delivery method should be used to deliver such selected pharmaceutical into the injured person. Preferably, a handheld computing device with A-D converters which provide the electrical signals attached to the emitters and detectors, containing the software which operates the emitter and sensors, operates the analysis of the signals database, operates the chemical substance analysis, and operates the immediate therapy selection and delivery decision-making processes, said computer being part of a kit which contains the computer, the emitters and detectors and associated connectivity, the pharmaceuticals, the pharmaceutical delivery methods and such other elements as are necessary to fully realize the utilize the invention. Figure 1 presents an overview description of the invention.

In view of the teaching presented herein, other modifications and variations of the present invention will readily be apparent to those of skill in the art. The discussion and description are illustrative of some embodiments of the present invention, but are not meant to be limitations on the practice thereof. It is the following claims, including all equivalents, which define the scope of the invention.

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Any patents, applications or publications mentioned in the specification are indicative of the levels of those skilled in the art to which the invention pertains. These patents, applications and publications are herein incorporated by reference to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.



## CLAIMS

1           1.     An apparatus for detecting, analyzing and treating a neurological injury in a  
2     subject, said apparatus comprising:

3                 a computing device comprising:

4                     at least one signal emitter attachable to a first position on the subject and  
5     operative to emit an electrical signal generated by the computing device into the subject such that  
6     the electrical signal is communicated to at least one nerve in close proximity to the first position,  
7     and wherein the at least one nerve is operative to transmit the electrical signal to a second  
8     position on the subject;

9                     at least one signal detector attachable to the second position on the subject and  
10    operative to detect the electrical signal transmitted by the at least one nerve;

11                    a database having at least one reference signal wherein the computing device is  
12    operative to compare the detected electrical signal to the at least one reference signal and  
13    indicate neurological injury when the at least one reference signal and the detected electrical  
14    signal exceed a predetermined threshold; and

15                    wherein the computing device is operative to provide instruction for selecting and  
16    administering a pharmaceutical into the subject to treat the indicated neurological injury.

1           2.     The apparatus of claim 1 further comprising a biochemical analyzer operative to  
2     sample a biochemical substance obtained from the subject and indicate the presence of  
3     neurological injury.

1           3.     The apparatus of claim 1 wherein the database is comprised of signal strengths for  
2 various positions and muscle groups of the subject.

1           4.     The apparatus of claim 1 wherein the computing device is further operative to  
2 provide a user with instruction for positioning the at least one emitter and the at least one  
3 detector on the subject.

1           5.     The apparatus of claim 2 wherein the biochemical analyzer is a portable blood  
2 and chemical analyzer.

1           6.     The apparatus of claim 2 wherein the computing device is further operative to  
2 provide instruction for selecting and administering pharmaceutical treatment based on a  
3 combined injury analysis derived from the detected electrical signal and the biochemical  
4 analyzer.

1           7.     The apparatus of claim 1 being comprised within a neurological kit having at least  
2 one device for introducing the pharmaceutical into the subject.

1           8.     The apparatus of claim 1 wherein the computing device is a handheld computer.

1           9.     A method for detecting and treating a neurological injury in a subject using the  
2 apparatus of claim 1, said method comprising the steps of:

3           attaching the at least one emitter and the at least one detector to the subject;

4           emitting an electrical signal from the computing device into the subject at the first  
5 position;

6           detecting the electrical signal transmitted by the at least one nerve at the second position;

7           comparing the detected electrical signal with the at least one reference signal in the  
8 database;

9           indicating a neurological injury when the detected electrical signal and the at least one  
10 reference signal exceed a predetermined threshold; and

11          providing instruction to a user for selecting and administering a pharmaceutical to the  
12 subject for treating the neurological injury.

1           10.    The method of claim 9 further comprising the step of using a biochemical  
2 analyzer to sample a biochemical substance obtained from the subject and indicate the presence  
3 of neurological injury.

### ABSTRACT OF THE DISCLOSURE

According to the present invention, there is disclosed a system and method for actively and passively detecting and analyzing neurological damage in an injured person using electrical and chemical analyses supported by a computer system and database, selecting an appropriate  
5 neurologically protective pharmaceutical for that injury type and circumstances based on the result of said analyses, and then delivering this pharmaceutical via direct injection, intravenous delivery, or other means into the person using components of the kit of which all the elements of the invention are a part.

## Neuro passive active kit illustration

